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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/892,061 | 06/26/2001 | Nicholas R. Bachur JR. | P-5026 | 1747 |

63863 7590 02/11/2008

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| EXAMINER | |
|---|---|
| BEISNER, WILLIAM H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1797 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 02/11/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/892,061 | BACHUR ET AL. | |
| | Examiner | Art Unit | |
| | WILLIAM H. BEISNER | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *113-115,117-122 and 146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *117,118 and 146* is/are allowed.

6)☒ Claim(s) *113-115 and 119-122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 113-115, 121 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US

4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691), Wong (US 4,730,112) and Allen (Measurement Science and Technology).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector. With respect to the claimed plurality of containers and modules with a plurality of openings, the reference of Sussman et al. discloses the use of a module (track) with openings for holding a plurality of containers (See column 3, lines 49-61).

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas is exists in the container, instant claim 113 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al. discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that “Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and

vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are "tunable" over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 113 further differs by reciting that other gas components other than carbon dioxide are detected by the detection system. Specifically, the laser emits radiation at a wavelength at which oxygen, ammonia, hydrogen sulfide, methane or sulfur dioxide absorbs radiation.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Ahnell et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See column 7, lines 34-48).

The reference of Wong discloses that it is known in the art to employ diode lasers to detect oxygen within a gas sample (See column 5, lines 12-59).

The reference of Allen discloses that it is known in the art to employ diode lasers to detect gases including ammonia, methane, hydrogen sulfide and sulfur dioxide within a gas sample (See page 14, first full paragraph and page 33, lines 8-11).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide, for example oxygen, within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. The use of a diode laser system as disclosed by Wong or Allen would provide art recognized diode lasers capable of detecting the gases suggested by Ahnell while providing the benefits associated with a diode laser verses an FTIR system of Sussman as discussed previously.

Finally claim 113 differs by requiring that the device includes a plurality of lasers and detectors wherein each laser emits radiation at a substantially single wavelength that is different from the other lasers.

As discussed above, the references of Sussman and Ahnell suggest that gases other than carbon dioxide can be detected within the culture vessels. In the absence of a showing of criticality and/or unexpected results, when detecting for a plurality of different gas components within the culture vessel as suggested by the references of Sussman and Ahnell, it would have been obvious to one of ordinary skill in the art to provide a plurality of laser/detector pairs that correspond to the specific gas components to be detected for the known and expected result of eliminating the need to tune a single diode laser through a plurality wavelengths and facilitating the detection of the desired gas components.

Note the system as discussed above would be capable of determining the presence and/or concentration of the gas components in the container

With respect to claim 114, the laser suggested by the prior art would be a monomodal laser.

With respect to claim 115, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 121, the reference of Sussman optically analyzes the neck portion of the sample vial.

With respect to claim 122, if the reference of Sussman does not inherently disclose a bracket for holding the light emitter and detector while the containers pass by, it would have been well within the purview of one having ordinary skill in the art to provide the device with a bracket for holding the sensing components of the device while the container pass by the detection system.

5. Claims 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691), Wong (US 4,730,112) and Allen (Measurement Science and Technology) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al., Wong and Allen has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

***Allowable Subject Matter***

6. Claims 117, 118 and 146 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter:

While the prior art rejections of record suggest a system that includes a bracket or housing for holding a plurality of lasers and detectors for movement relative to a plurality of culture containers, the prior art of record fails to teach or fairly suggest the features of claims 116-118 including a housing for holding the plurality of laser and detectors wherein the housing is movable between a plurality of container and wherein the lasers and detectors are also movable within the movable housing.

***Response to Arguments***

8. With respect to the rejection of Claims 113-115, 121 and 122 under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691), Wong (US 4,730,112) and Allen (Measurement Science and Technology), Applicants argue that the rejection is improper for the following reasons:

i) The reference of Sussman et al. teaches away from the claimed invention (See pages 7-8 of Applicants' response filed 11/13/2007). Applicants stress that the container material described by Sussman et al. is optically transparent over an extremely narrow range of wavelengths in the UV spectrum and thus teaches away from the concept of a container with a wide range of optical transparency that would permit the use of a plurality of lasers that emit at different wavelengths to detect gases that absorb at distinct and different wavelengths. Applicants also stress that the reference of Sussman et al. does not disclose the claimed 2.004 micron wavelength required of the instant claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the references that suggests the modifications resulting in a device that meets the instant claims. With respect to the material of the sample container, while the reference of Sussman et al. discusses the use of polymethylpentene as a possible material of the container, the reference also clearly states that "The culture container must have a "window" for infrared transmittance with a bandwidth suitable for detecting the gaseous product of metabolism" (See column 4, lines 32-34). The reference also states that "borosilicate glass vials and soda lime glass vials have been found to be useful" (See column 4, lines 41-47). In view of these disclosures, one of ordinary skill in the art would have recognized that the container is not limited to the use of polymethylpentene as argued by Applicants, especially when detecting metabolic gases other than carbon dioxide which is suggested by the prior art of record. It is also noted that the references of Veale and Allen evidence that one of ordinary skill in the art would recognize that a container material must be used that is optically transparent to the wavelengths of light employed (See column 4, lines 22-31, of Veale and page 21 of Allen). Finally note instant claim 113 is not limited to a device that requires this single wavelength. Claim 113 can include a device that only detects oxygen and ammonia and as a result, the prior art does not have to disclose the 2.004 micron wavelength to meet the instant claim limitations.

ii) The references of Wrobel et al., Noller, and Veale fail to teach or suggest the use of a plurality of lasers, the use of an optically transparent container at the plurality of wavelengths,

and the references fail to make up for the deficiencies previously discussed with respect to the reference of Sussman (See page 9 of Applicants' response filed 11/13/2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the references that suggests the modifications resulting in a device that meets the instant claims.

iii) The references of Ahnell et al., Wong and Allen fail to teach or suggest the use of a plurality of lasers, the use of an optically transparent container at the plurality of wavelengths, and the references fail to make up for the deficiencies previously discussed with respect to the reference of Sussman (See page 9 of Applicants' response filed 11/13/2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the references that suggests the modifications resulting in a device that meets the instant claims.

9. With respect to the rejection of Claims 119 and 120 under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US

4,073,691), Wong (US 4,730,112) and Allen (Measurement Science and Technology) and taken further in view of Berndt et al.(US 5,518,923), Applicants' (See pages 10-11 of Applicants' response filed 11/13/2007) stress that the additional references of record fail to make up for the deficiencies related to the reference of Sussman et al.

In response, the additional references were merely relied upon to address the additional claim limitations recited in the dependent claims.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-

1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

WHB